FEB 1 3 2004

K040243

SUMMARY OF SAFETY AND EFFECTIVENESS

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based as follows:

A. Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, Arizona 85280
Phone:	480-303-2752
Fax:	480-449-2546
Contact:	Aymee R. Berry, Associate Manager, Regulatory Affairs

B. Device Name: Bard® Atlas™ PTA Balloon Dilatation Catheter

Common or Usual Name: Catheter, Percutaneous

Classification: Class II

C. Predicate Device Name(s): Bard® Conquest™ PTA Balloon Dilatation Catheter (K014212, cleared 01/17/02)

Bard™ Opti-Plast® Centurion™ 5.5F PTA Catheter (K973013, cleared 06/19/98)

D. Device Description:

The Bard® Atlas™ PTA Balloon Dilatation Catheter is a coaxial lumen catheter with a balloon mounted on its distal tip. One lumen accommodates the insertion guidewire and the second provides a channel for inflation/deflation of the balloon. There are two radiopaque marker bands placed beneath the balloon to indicate its position within the vasculature.

E. Statement of Intended Use:

The Bard® Atlas™ PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the iliac arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

F. Substantial Equivalence:

A variety of tests, assessments, and comparisons demonstrate that the Bard® Atlas™ PTA Balloon Dilatation Catheter is substantially equivalent to the above-referenced predicates in terms of composition, design, intended use, and performance attributes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2004

C.R. Bard, Inc.
c/o Ms. Aymee R. Berry
Associate Manager, Regulatory Affairs
Bard Peripheral Vascular
1625 West 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

Re: K040243
Bard Atlas PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: February 2, 2004
Received: February 3, 2004

Dear Ms. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Diana R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040243

Device Name: Bard™ Atlas™ PTA Balloon Dilatation Catheter

Indications For Use: The Bard® Atlas™ PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the iliac arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040243